510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE TEMPLATE

A. 510(k) Number: k033379

B. Analyte: Special Chemistry Control – Acid Phosphatase, Lactate, Lipase, Pancreatic Lipase, Cholinesterase, and Direct TIBC

C. Type of Test: N/A

D. Applicant: Bayer Healthcare

E. Proprietary and Established Names: Bayer ADVIA 1650 Special Chemistry Control

F. Regulatory Information:

1. Regulation section: 21 CFR 862.1660

2. Classification: Class I

3. Product Code: JJY

4. Panel: 75

G. Intended Use:

1. Indication(s) for use: For *in vitro* diagnostic use in the control of ADVIA Chemistry systems for certain chemistry methods.

2. Special condition for use statement(s): none

3. Special instrument Requirements: Bayer ADVIA Systems

H. Device Description: The Bayer Special Chemistry Controls are two separate levels of quality control material prepared from human serum with non-serum constituents added.

I. Substantial Equivalence Information:

1. Predicate device name(s): Bayer Special Chemistry Control

2. Predicate K number(s): k030801

3. Comparison with predicate:

DEVICE	PREDICATE
A. Similarities	
Analyte Constituents Acid Phosphatase, Lactate, Lipase, Pancreatic Amylase, Cholinesterase, and Direct TIBC*	**Analyte Constituents** Acid Phosphatase, Lactate, Lipase, Pancreatic Amylase, Cholinesterase, and Direct TIBC with newly assayed values for Direct TIBC
Performance of above analytes Meets medical decision levels	**Performance of above analytes** Meets medical decision levels
Source material Human Serum	**Source material** Human Serum
Storage and Handling Unreconstituted 2-8^{0}C Reconstituted 2-8^{0}C, 7 days	**Storage and Handling** Unreconstituted 2-8^{0}C Reconstituted 2-8^{0}C, 7 days
Instructions for use Use the control material according to directions accompanying the instrument or assay prior to use. Treat the control material in the same manner as patient samples.	**Instructions for use** Use the control material according to directions accompanying the instrument or assay prior to use. Treat the control material in the same manner as patient samples.
Limitations The results obtained depend on several factors: erroneous results can occur from improper storage, reconstitution errors, inadequate mixing, or sampling handling errors. Do not use if there is visible evidence of microbial growth in the vial.	**Limitations** The results obtained depend on several factors: erroneous results can occur from improper storage, reconstitution errors, inadequate mixing, or sampling handling errors. Do not use if there is visible evidence of microbial growth in the vial.

* The predicate device contained Direct TIBC as an analyte so the manufacturing did not change, however Bayer did not assign values for the Direct TIBC at the time of the predicate device. This submission only includes information relevant to the value assignment of Direct TIBC.

J. Standard/Guidance Document Referenced (if applicable) Guidance for Industry – Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material

K. Test Principle: N/A

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:* N/A

    b. *Linearity/assay reportable range:* N/A

    c. *Traceability (controls, calibrators, or method):* stored master lot

    d. *Detection limit (functional sensitivity:* N/A

    e. *Analytical specificity:* N/A

    f. *Assay cut-off:* N/A

2. Comparison studies:
    a. *Method comparison with predicate device:* Control Material is identical to predicate device with the exception of assayed values for Direct TIBC.

    b. *Matrix comparison:* Control Material is identical to predicate device with the exception of assayed values for Direct TIBC

3. Clinical studies:
    a. *Clinical sensitivity:* N/A

    b. *Clinical specificity:* N/A

4. Clinical cut-off: N/A

5. Expected values/Reference range: The value assignment of the test lot is based upon the ratio of the stored master lot's observed mean to the original assigned mean.

M. Conclusion: Based upon the information provided, I recommend that the Bayer Special Chemistry Control for the ADVIA Chemistry systems be found substantially equivalent with the predicate devices as defined in 21 CFR 862.1660.